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09/248,438 02/11/99 MAYTOM

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EXAMINER

MOEZIE, M

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

04/25/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/248,438

Applicant(s)

Maytom et al.

Examiner

M. MOEZIE

Group Art Unit

1617

☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-10 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant is advised that should claims 3-4 be found allowable, claims 5-6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper tames extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-36 of copending Application No. 08/549,792. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the U.S. application Serial No. 08/549,792, similar<sup>to the instant claims,</sup> are drawn to methods of treating sexual dysfunction broadly and male erectile dysfunction, more specifically, which employ vasoactive cGMP-PDE inhibiting compounds of formula (I) broadly and sildenafil, more specifically.

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The instant claims differ primarily in that the animal host to be treated has an injured spinal cord.

One of ordinary skill would have found it obvious to employ the instant compounds to treat sexual dysfunctions in a host with an injured spinal cord since any animal host suffering from sexual dysfunction would be reasonably expected to exhibit a similar therapeutic sexual dysfunction treatment effect on the administration of the vasoactive, cGMP-PDE inhibiting compounds herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/28902 in view of Doherty, Jr., et al..

WO 94/28902 teaches that the compounds of the claims are vasoactive compounds, known to be useful in the treatment of male erectile, sexual dysfunction. See, e.g., the abstract, page 2, and page 17 therein.

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The instant claims differ primarily in that they are drawn to methods for the treatment of animal hosts with an injured spinal cord.

One of ordinary skill at the time the invention was made would have found it obvious to employ the instant compounds in methods of treating sexual and/or male erectile dysfunctions in hosts having an injured spinal cord.

One of ordinary skill would have been motivated to employ the instant compounds to treat sexual dysfunctions in hosts with an injured spinal cord since any animal host suffering from sexual dysfunctions or male erectile dysfunction would be reasonably expected to exhibit a similar therapeutic sexual dysfunction treatment effect on the administration of the instant known vasoactive compounds. This assertion is supported by Doherty, Jr. et al. which suggests that the cGMP-PDE inhibitor, sildenafil, is useful to treat erectile, sexual dysfunctions in various hosts, including those suffering from neurogenic impotence associated with spinal cord injury. See, e.g., column 1, lines 54-55, column 5, lines 41-54 and claims 1-2 and therein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Moezie, whose telephone number is (703) 308-4612. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Moezie, J. D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

M. Moezie:jmr

April 13, 2000

  
MINNA MOEZIE  
PRIMARY EXAMINER